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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,136	10/10/2001	Dexu Zhu	524022000100	8877

25225            7590            12/30/2002  
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[REDACTED] EXAMINER

ZUCKER, PAUL A

[REDACTED] ART UNIT      [REDACTED] PAPER NUMBER

1621  
DATE MAILED: 12/30/2002      10

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/975,136	ZHU ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Paul A. Zucker	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 27 June 2002.

2a) This action is FINAL.                  2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-21 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>10</u> .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>7</u> .	6) <input type="checkbox"/> Other: _____

**DETAILED ACTION**

***Current Status***

1. This action is responsive to Applicants' amendment of 27 June 2002 in Paper No 8 and supplemental amendment of December 18 in Paper No 9.
2. Receipt and entry of Applicants' amendment is acknowledged.
3. Applicants' addition of new claim 21 is acknowledged.
4. Claims 1-21 remain outstanding.
5. The objection to the claims set forth in paragraph 3 of the previous Office Action in Paper No 4 is withdrawn in response to Applicant's amendment.
6. The rejections under 35 USC § 112, second paragraph, set forth in paragraphs 4 and 5 of the previous Office Action in Paper No 4 are withdrawn in response to Applicants' amendment.
7. The rejection under 35 USC § 102 (b) set forth in paragraph 6 of the previous Office Action in Paper No 4 is withdrawn in view of Applicants' amendment of the claims.
8. Applicants' declaration under 37 CFR 1.32 has been carefully considered and the rejection under 35 USC § 103 set forth in paragraph 7 of the previous Office Action in Paper No 4 has withdrawn been withdrawn in response thereto. The declaration in combination with Applicant's arguments was persuasive with regard to there being no suggestion to one of ordinary skill in the art to combine the
9. The rejection under 35 USC § 103 set forth in paragraph 7 of the previous Office Action in Paper No 4 is withdrawn in favor of the new rejection below. Applicants' arguments with regard to this rejection are therefore rendered moot.

***New Objections and Rejections***

***Allowable Subject Matter***

10. The verbal indication of allowability of claims 1-21 is withdrawn in view of the newly combined references: Kamoda et al (US 6,284,791 09-2001) and Satoh et al (US 4,732,916 03-1988). A rejection based on the newly combined references follows.

***Specification***

11. The abstract of the disclosure is objected to because it does not summarize the contribution that the instant invention makes to the art. Applicants should include a description (chemical name or structure) of the compounds of the invention. Correction is required. See MPEP § 608.01(b).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Objections***

12. Claims 8 and 9 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim since claims 8 and 9 each depend upon two claims (5 and 2, 5 and 3, respectively). See MPEP § 608.01(n).

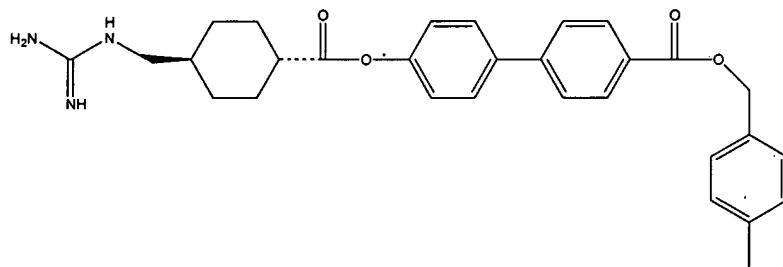
***Claim Rejections - 35 USC § 112***

13. Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention. Claim 1 recites the limitation "C<sub>6</sub>-C<sub>10</sub>" in line 4. Claim 1 and its dependents are therefore rendered indefinite. It is suggested that Applicants add the word "aryl" after the indicated limitation.

***Claim Rejections - 35 USC § 103***

14. Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamoda et al (US 6,284,791 09-2001) and further in view of Satoh et al (US 4,732,916 03-1988). Kamoda teaches (Column 20, lines 36-61) the following compound as a racemic mixture:



This corresponds to Applicant's claimed compound of instant claim 2 with the exception that the cyclohexane ring is replaced by an aromatic benzene ring. Kamoda further teaches (Column 37, lines 33-64, Table 1, 14<sup>th</sup> entry) the activity of the compound against *Helicobacter pylori* and *Eschericia coli*. Kamoda teaches (Column 12, line 57- column 13, line 31) methods of treatment and pharmaceutical compositions (with excipients, etc.) of the compounds disclosed for oral administration to humans. Kamoda further teaches (Column 1, line 33 – column 2, line 5) combination therapies using the combination of antibiotics such as amoxicillin and omeplazol, lansoplazol (anti-*H. pylori* agents) which comprises inhibition activity

to a proton pump and are used in clinics as anti-ulceration agents and compounds containing the guanidine group to treat conditions such as gastritis. The use against resistant strains is implicit in the teaching of combination therapies. The Examiner also notes that the addition of written matter does not impart patentability to a kit which corresponds to obvious and, in fact, required packaging for use of the invention by a physician.

The difference between the instant invention and that taught by Kamoda is that Kamoda does not suggest replacing the saturated cyclohexane ring with an aromatic benzene ring.

Satoh, however, teaches (Column 1, lines 17-44) that the replacement of the cyclohexane ring in the compounds of Kamoda with an aromatic benzene ring results in an increase in anti-ulcer activity and a decrease in toxicity. Satoh's teaching can therefore be seen as a suggestion to modify the compounds disclosed by Kamoda to arrive at the instant compound of claim 3.

Thus the instantly claimed compounds and methods would have been obvious to one of ordinary skill in the art. The motivation would have been to produce an anti-ulcer treatment that was more effective (increased potency) and less toxic. The expectation for success would have been high since Satoh teaches the instant modification of Kamoda's compounds.

***Conclusion***

15. Claims 1-21 are outstanding. Claims 1-21 are rejected.

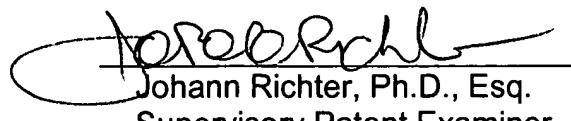
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 703-306-0512. The examiner can normally be reached on Monday-Friday 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 703-308-4532. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Paul A. Zucker  
Patent Examiner  
Technology Center 1600

December 30, 2002



Johann Richter, Ph.D., Esq.  
Supervisory Patent Examiner  
Technology Center 1600